The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

MAILED

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

JUL 1 7 2001

Ex parte CARL E. HANSON

PAT. & T.M. OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

Appeal No. 2000-1697 Application No. 08/903,677

ON BRIEF

Before CALVERT, ABRAMS, and NASE, <u>Administrative Patent Judges</u>. ABRAMS, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-17, which are all of the claims pending in this application.

We AFFIRM.

BACKGROUND

The appellant's invention relates to a method of preventing the reoccurrence of chest pain associated with the heart (claims 1-8) and a method of treating angina pectoris (claims 9-17). An understanding of the invention can be derived from a reading of exemplary claim 1, which appears in the appendix to the appellant's Brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Dapcich-Miura et al. "Contingency Management of Adherence to a Complex Medical Regimen in an Elderly Heart Patient," <u>Behavior Therapy</u>, Vol. 10, pages 193-201, 1979 (Dapcich-Miura)

Riemersma et al. "Risk of angina pectoris and plasma concentrations of vitamins A, C, and E and carotene," <u>The Lancet</u>, Vol. 337, No. 8732, pages 1-5, 1991 (Riemersma)

Singh <u>et al.</u> "Usefulness of Antioxidant Vitamins in Suspected Acute Myocardial Infarction (The Indian Experiment of Infarct Survival-3," <u>The American Journal of Cardiology</u>, Vol. 77, pages 232-236, 1996 (Singh)

Langtry et al. "Nisoldipine Coat-Core: A Review of its Pharmacodynamic and Pharmacokinetic Properties and Clinical Efficacy in the Management of Ischemic Heart Disease," <u>Drugs</u>, Vol. 53(5), pages 867-884, 1997 (Langtry)

Claims 1-17 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the appellant regards as the invention.

Claims 1-17¹ stand rejected under 35 U.S.C. § 102(b) as being anticipated by Singh, Langtry, Riemersma or Dapcich-Miura or, in the alternative, under 35 U.S.C. § 103(a) as being unpatentable over Singh, Langtry, Riemersma or Dapcich-Miura.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the Answer (Paper No. 15) for the examiner's complete reasoning in support of the rejections, and to the Brief (Paper No. 14) for the appellant's arguments thereagainst.

<u>OPINION</u>

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

¹Although listed in the final rejection (Paper No. 12) and the Answer as including "claims 1-7," it would appear that this is an inadvertent typographical error on the part of the examiner, and correctly should read "claims 1-17." Noting that the appellant has not raised this as an issue, we have considered this rejection as pertaining to claims 1-17.

At the outset, we point out that since the appellant has chosen to allow all of the claims to stand or fall together (Brief, page 3), with regard to each of the rejections we need only consider claim 1, which we have selected as the representative claim.

The Rejection Under The First Paragraph Of Section 112

Although not stated in so many words, it would appear that the examiner's rejection is grounded in the belief that the claims are not supported by an enabling disclosure, rather than a failure to describe the invention. An analysis of whether the claims under appeal are supported by an enabling disclosure requires a determination of whether that disclosure contained sufficient information regarding the subject matter of the appealed claims as to enable one skilled in the pertinent art to make and use the claimed invention. The test for enablement is whether one skilled in the art could make and use the claimed invention from the disclosure coupled with information known in the art without undue experimentation. See United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), and In re Stephens, 529 F.2d 1343, 1345, 188 USPQ 659, 661 (CCPA 1976).

The examiner has set forth two reasons why the claims are not supported by an enabling disclosure. The first is that the appellant has given no proof that the method recited in the claims actually works. To this, the appellant has responded by pointing out where in the specification such a result is substantiated, as well as asserting that the examiner's challenge does not have adequate support and therefore the burden

has not shifted to the appellant to provide rebuttal evidence (Brief, pages 3 and 4). In this regard, it would appear that the examiner actually is challenging the utility of the appellant's invention, although such a rejection under 35 U.S.C. § 101 has not been made. We note that the appellant has asserted a specific utility for the invention, while the examiner has not provided evidence that the asserted utility is not credible.² Of interest here is the fact that the examiner professes that the references applied against the merits of the claims teach that citrus juices have a beneficial effect upon chest pain, which would seem, at least in the broad sense, to mitigate against an attack upon the appellant's invention based upon lack of credible utility.

The examiner's second reason for this rejection is that the specification does not inform the reader what is considered to be the "effective amount" of the lime juice and what constitutes the "active ingredients" of the lime juice. With regard to "effective amount," it seems clear that this amount is that which alleviates the chest pain, for such is stated in claim 1 and is explained on page 4 of the specification as being the amount that needs to be taken to have a "beneficial effect" on the heart after noticing the chest pain. The appellant has discussed the amount that worked for him on pages 4 and 5 of the specification, which can be presumed to be a guide for all users.

The situation with regard to "active ingredients" is not so straightforward. The appellant has chosen to define "lime juice" in the specification as meaning not only lime

²See Section 706.03(a)(1) of the Manual of Patent Examining Procedure.

juice itself but, inter alia, "the active ingredients in the lime that counter the chest pain or anginal attack" (page 2, line 22) and, in view of this definition, what constitutes "active ingredients" is material to the subject matter of all of the claims, including claim 1. The appellant has not responded in the Brief to the examiner's questioning on page 3 of the final rejection with regard to "active ingredients," and therefore the examiner's position that the absence of information regarding this terminology causes the claims not to be enabled is uncontroverted.

The rejection of claims 1-17 under 35 U.S.C. § 112, first paragraph, is sustained.

The Rejection Under The Second Paragraph Of Section 112

Claims 1-17 are rejected under this section of the statute also. The issues noted by the examiner are the same as those pointed out with regard to the rejection under the first paragraph of Section 112.

We recognize that the appellant is free to claim the invention in broad terms, and is entitled to the broadest reasonable interpretation of the claim language. However, because a patentee has the right to exclude others from making, using and selling the invention covered by the patent, the public must be apprised of exactly what the patent covers, so that those who would approach the area circumscribed by the claims of a patent may more readily and accurately determine the boundaries of protection involved and evaluate the possibility of infringement and dominance. It is to this that the second

paragraph of Section 112 is directed. See In re Hammack, 427 F.2d 1378, 1382, 166
USPQ 204, 208 (CCPA 1970). The second paragraph of 35 U.S.C. § 112 requires
claims to set out and circumscribe a particular area with a reasonable degree of
precision and particularity. See, for example, In re Johnson, 558 F.2d 1008, 1015,
194 USPQ 187, 193 (CCPA 1977). In making this determination, the definiteness of
the language employed in the claims must be analyzed, not in a vacuum, but always in
light of the teachings of the prior art and of the particular application disclosure as it
would be interpreted by one possessing the ordinary level of skill in the pertinent art. Id.

Claim 1 reads as follows:

- 1. A method of preventing the reoccurrence of chest pain associated with the heart, which method comprises:
- (a) noticing a pain in the chest; and then shortly thereafter
- (b) taking an effective amount of lime juice into the body to alleviate the chest pain.

As was the case with the other Section 112 rejection, the examiner has focused upon "active ingredients" and "effective amount," this time as causing the claims to be indefinite. As we stated above with regard to the first paragraph rejection, it is our view that the appellant has provided guidance for interpreting "effective amount," and therefore we find that it is not indefinite under the second paragraph.

While "active ingredients" explicitly appears only in dependent claims 15 and 17, it is implicitly included in all of the claims because the appellant has chosen to define "lime juice" in the specification as

lime juice <u>or</u> limeade <u>or</u> any combination that includes the juice of a lime whether in concentrated or diluted form <u>or</u> that includes the active ingredients in the lime that counter the chest pain or anginal attack (page 2, lines 20-22, emphasis added).

However, there is no explanation in the specification of what constitute the ingredients in lime juice which cause it to alleviate chest pain, and this is one of the issues raised by the examiner in this rejection. The specification merely informs the reader that

[p]ersons skilled in the art of purification and/or pharmacology <u>may</u> also locate the active ingredient(s) in the lime and administer those ingredient(s) in purified form or otherwise to persons who suffer from chest pain (page 3, line 30 <u>et seq.</u>, emphasis added).

From our perspective, the failure of the appellant to disclose the "active ingredients" that are defined as being one manifestation of the "lime juice" recited in the claim renders the metes and bounds of claim 1 indeterminable with a reasonable degree of precision and particularity. We are not persuaded otherwise by the arguments presented on page 5 of the Brief.

The rejection of claims 1-17 under 35 U.S.C. § 112, second paragraph, is sustained.

The Rejection Under Section 102

All of the claims stand rejected as being anticipated by any one of Singh,
Langtry, Riemersma or Dapcich-Miura. Anticipation is established only when a single
prior art reference discloses, either expressly or under the principles of inherency,
each and every element of the claimed invention. See In re Paulsen, 30 F.3d 1475,
1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) and In re Spada, 911 F.2d 705, 708,
15 USPQ2d 1655, 1657 (Fed. Cir. 1990).

None of the applied references mention lime juice at all, much less disclose or teach a method of preventing chest pain or of treating angina pectoris by means of a method that includes taking lime juice shortly after an episode thereof. This being the case, it is clear that the appellant's claims are not anticipated by any of the applied references, and we will not sustain this rejection.

The Rejection Under Section 103

Claims 1-17 also stand rejected as being unpatentable over any one of Singh,
Langtry, Riemersma or Dapcich-Miura, it being the examiner's position that each one of
these references suggests that chest pain can be alleviated by taking vitamin C or fruit
juices, and in the absence of evidence that lime juice provides any special advantage, it
would have been obvious to one of ordinary skill in the art to substitute lime juice for

one of the other juices mentioned in the references. The examiner considers the claimed dose to be a matter of choice.

Among the arguments raised by the appellant is that none of the references would have suggested to one of ordinary skill that a dose of citrus juice, much less lime juice, be taken shortly after noticing a pain in the chest. The examiner has not pointed out where basis exists in any of the references for this teaching, and we are at a loss to locate such on our own. Singh teaches administering doses of vitamin C to persons suffering from chest pains over a period of time (page 233), and opines that such "might" provide protection against angina (page 236). Langtry makes no mention of fruit juice, except to state that concurrent taking of grapefruit juice adversely affected the drug being tested to manage ischemic heart disease (page 869). Concentrations of vitamin C were administered in the Riemersma project, and the conclusion reached was that the less the antioxidant intake, the greater the risk of angina pectoris (page 3).

Dapcich-Miura administered orange juice over an extended period of time and concluded that, along with exercise, a controlled diet and medications, the frequency of angina decreased (page 193).

From our perspective, none of the references establish a <u>prima facie</u> case of obviousness with respect to the subject matter recited in independent claims 1 and 9,

which require that the lime juice be taken "shortly thereafter" an incident of chest pain or angina. This being the case, we will not sustain the Section 103 rejection of claims 1-17.

SUMMARY

The rejection of claims 1-17 under 35 U.S.C. § 112, first paragraph, is sustained.

The rejection of claims 1-17 under 35 U.S.C. § 112, second paragraph, is sustained.

The rejection of claims 1-17 under 35 U.S.C. § 102(b), is not sustained.

The rejection of claims 1-17 under 35 U.S.C. § 103(a), is not sustained.

The rejection of each of the claims having been sustained, the decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

IAN A. CALVERT

Administrative Patent Judge

NEAL E. ABRAMS

Administrative Patent Judge

JEFFREY V. NASE

Administrative Patent Judge

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